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UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

SEKISUI AMERICA CORPORATION and SEKISUI MEDICAL CO. LTD., Plaintiffs, v. RICHARD HART and MARIE LOUISE TRUDEL-HART, Defendants.	12 Civ. 3479 (SAS) (FM)
RICHARD HART and MARIE LOUISE TRUDEL-HART, Plaintiffs, v. SEKISUI AMERICA CORPORATION and SEKISUI MEDICAL CO. LTD., Defendants.	12 Civ. 3560 (SAS) (FM)

DEFENDANTS' MOTION *IN LIMINE* TO EXCLUDE THE EXPERT REPORT AND TESTIMONY OF CARRIE M. KUEHN

Defendants Richard Hart and Marie Louise Trudel-Hart (the "Harts") submit this motion *in limine* to exclude the expert report and testimony of Carrie M. Kuehn, pursuant to Federal Rule of Evidence 702.

BACKGROUND

Plaintiffs proffer Ms. Kuehn as an expert in compliance with the Quality System Regulations ("QSRs") governing medical device manufacturers, which are promulgated by the United States Food & Drug Administration ("FDA"). Ms. Kuehn opines that, "between 2006 and April 20, 2009, ADI lacked a functioning or FDA-compliant Quality Management System (QMS) required for a manufacturer of [in vitro diagnostic ("IVD")] medical devices."[1] Exhibit ("Exh.") 1 to Declaration of Siobhan Briley ("Briley Decl.") (Expert Report of Carrie M. Kuehn, Oct. 18, 2013 ("Kuehn Report")) at 4. The Kuehn Report is "based on [Ms. Kuehn's] education and experience." *Id.* at 2.

Ms. Kuehn has no experience or training in auditing or inspecting medical device manufacturing companies. She has never worked for the FDA or any other regulatory agency. *See id.* at 1-2 & Appendix ("App.") A; Exh. 2 to Briley Decl. (Transcript of Deposition of Carrie M. Kuehn, Aug. 22, 2013) at 12:2-3. She has never worked for a medical device manufacturing company, held a position in quality assurance or regulatory affairs, or been present for an FDA inspection. *See id.*; *see also* Exh. 2 to Briley Decl. at 6:7-10:23. She has never served as a client liaison for an FDA inspection. *See id.* The sole basis for her claimed expertise is certification

[1] Ms. Kuehn lists six other "main opinions." All are simply subsets of the quoted opinion. *Id.* at 4.

from the Regulatory Affairs Professional Society ("RAPS")—certification available to anyone who pays the fee and completes the online courses.[2] *See id.* at 1-2.

Ms. Kuehn has never audited or inspected American Diagnostica, Inc. ("ADI")—or any other medical device manufacturing company. *See id.*; Exh. 2 to Briley Decl. at 13:11-14:7. Her opinion in this case is founded entirely on her review of documents provided by Plaintiffs' counsel. *See, e.g.*, Exh. 1 to Briley Decl. at 19-25; *see also* Exh. 2 to Briley Decl. at 63:19-22. Through her review, Ms. Kuehn concluded that ADI failed to maintain a significant amount of documentation required to comply with the QSRs. *See, e.g.*, Exh. 1 to Briley Decl. at 19-22, 29, 34. She further concluded that, to the extent ADI did maintain documentation, it lacked information or signatures or was otherwise incomplete. On the basis of these document deficiencies, Ms. Kuehn concluded that, between 2006 and 2009—four to seven years ago—ADI was operating in flagrant violation of numerous FDA regulations. *See, e.g., id.* at 18, 22. This opinion is contrary to the findings of the FDA, all independent auditors who audited ADI in 2006, 2007, 2008 and 2009, and Morgan Lewis & Bockius LLP ("Morgan Lewis"), who performed due diligence for Plaintiffs prior to the acquisition. *See* Exhs. 3-12 to Briley Decl. (Oct. 17, 2005 FDA Establishment Inspection Report; Apr. 27, 2006 Intertek Systems Certification audit report; Feb. 5, 2007 Medical QMS Documentation Review Report; Mar. 21, 2007 Intertek Systems Certification audit report; April. 8-9, 2008 Intertek Systems Certification audit report; Apr. 14-16, 2009 Intertek Systems Certification audit report; Sept. 3, 2008 Trinity

[2] Anyone can become a member of RAPS. *See* http://www.raps.org/membership-amp-benefits/join-today.aspx. Anyone with a bachelor's degree can take the exam to obtain Regulatory Affairs Certification. *See* Exh. 12 to Briley Decl. (Regulatory Affairs Certification Candidate Guide, obtained from http://www.raps.org/rac/about-the-rac.aspx). Anyone willing to pay $2870 can complete the online courses to obtain a Regulatory Affairs Certificate: Medical Devices and Pharmaceutical. *See* Exh. 13 to Briley Decl. (Registration Form, obtained from http://www.raps.org/online-university/regulatory-affairs-certificate-program.aspx).

Biotech audit report; Dec. 10, 2007 Siemens Dade Behring audit report; Jan. 7, 2009 Preliminary Legal Due Diligence Report of Morgan Lewis). Ms. Kuehn does not explain how her document review provided the same information the FDA and other auditors gather during on-site inspections, or how it is that Morgan Lewis failed to identify even one of the deficiencies Ms. Kuehn identifies. The Kuehn Report contains no reasoning to support Ms. Kuehn's conclusion that the document deficiencies she identified constitute violations of FDA regulations.[3] Ms. Kuehn does not even explain how she determines that a document is deficient.

The Harts base this motion to exclude Ms. Kuehn's report and testimony on the reasoning and the legal materials cited by Plaintiffs in their motion *in limine* to exclude in part the report and testimony of the Harts' FDA expert, Thomas D. Becze. *See* Plaintiffs' Motion *in limine* to Exclude Portions of the Expert Report and Testimony of Thomas D. Becze, Dkt. 65, at 3. As shown below, and as will be further shown in the Harts' Opposition to Plaintiffs' motion, Mr. Becze is a qualified expert. Plaintiffs' purported expert, Ms. Kuehn, is not, and on the reasoning and authority cited by Plaintiffs, her report and testimony must be stricken.

ARGUMENT

An expert may be qualified to opine on "scientific, technical, or other specialized knowledge" if she has sufficient "knowledge, skill, experience, training or education" to assist the trier of fact. Fed. R. Evid. 702. Her testimony will be admitted only if it "is based on sufficient facts or data," it "is the product of reliable principles and methods," and she has

[3] Ms. Kuehn's methodology is premised on missing documents, but Ms. Kuehn does not address the fact that Plaintiffs destroyed documents in this case. Nor does she address the possibility that she has not reviewed all relevant documents. Indeed, as the Harts showed, Ms. Kuehn failed to find (or, if she found, identify) documents that would have affected her conclusions before submitting her initial report. *See* Exh. 14 to Briley Decl. (Expert Report of Thomas D. Becze, Aug. 5, 2013 ("Becze Report")), App. 3; Exh. 15 to Briley Decl. (Memorandum from Carrie M. Kuehn to Morrison & Foerster LLP, Oct. 17, 2013). Ms. Kuehn does not explain how, despite this significant flaw in her methodology, it is nonetheless reliable.

"applied the principles and methods reliably to the facts of the case." *Id.* Ms. Kuehn lacks the required "relevant specialized knowledge" to opine on compliance with the QSRs. *R.F.M.A.S., Inc. v. So*, 748 F. Supp. 2d 244, 251 (S.D.N.Y. 2010). Her opinion is not based on sufficient facts or data, and she does not employ reliable principles and methods. Her report and testimony should be excluded.

Ms. Kuehn has no experience, education, or training that qualifies her to opine that a medical device manufacturing company she has never inspected or audited was not in compliance with FDA regulations nearly a decade ago. Whatever knowledge she has of regulatory affairs she gained by completing an online RAPS course in 2011. *See* Exh. 1 to Briley Decl. at 1-2. Her experience as a consultant is not relevant to determining the compliance status of a medical device manufacturer. *See id.* at 1. Ms. Kuehn is not qualified to render the opinions in the Kuehn Report. *See R.F.M.A.S*, 748 F. Supp. 2d at 251-52 ("To determine whether a witness qualifies as an expert, courts compare the area in which the witness has superior knowledge, education, experience or skill with the subject matter of the proffered testimony.") (quoting *United States v. Tin Yat Chin*, 371 F.3d 31, 40 (2d Cir. 2004) (internal quotation marks omitted)).

In contrast to Ms. Kuehn, Defendants' FDA expert, Thomas D. Becze, has "33 years of medical device and pharmaceutical industry experience." Exh. 14 to Briley Decl. (Expert Report of Thomas D. Becze, Aug. 5, 2013 ("Becze Report")), App. 1. He has "[s]erved as an on-site liaison during 107 FDA facility (establishment) inspections," and is a recognized expert in "facility inspection/qualification of finished pharmaceutical, medical device, and veterinary medicine production including [Quality Control] laboratories and [Active Pharmaceutical Ingredient] facilities." *Id.* at 2. He has composed, assembled, and submitted to the FDA

seventy-four "IDEs, PMAs, and 510(k)s."[4] *Id.* He has held "positions in medical device and pharmaceutical quality assurance and regulatory affairs." *Id.* at 1.

Nonetheless, Plaintiffs argue that Mr. Becze "lacks any experience either with the FDA or overseeing the 510(k) submission process" and is therefore not qualified to rebut Mr. Ulatowski's opinion that the Femtelle 510(k) was "destined to fail." Dkt. 65 at 5. They assert that Mr. Becze fails to show how his experience informs his opinions. *Id.* By Plaintiffs' reasoning, Ms. Kuehn's report and testimony must also be excluded.[5] *See Mahoney v. JJ Weiser & Co.*, No. 04 Civ. 2592(VM), 2007 WL 3143710, at *5 (S.D.N.Y. Oct. 25, 2007) ("Where, as here, an expert's opinion is based on the expert's experience, courts focus on the relationship between the experience and the opinion and whether the latter is rationally related to the former.") (citation omitted)).

Plaintiffs further argue that Mr. Becze's testimony should be excluded because it is "neither based on sufficient facts or data nor the product of reliable principles and methods." Dkt. 65 at 4. Plaintiffs' logic compels the exclusion of Ms. Kuehn's testimony. The Kuehn Report is a compilation of observations about the documents Ms. Kuehn reviewed followed by

[4] IDEs, PMAs and 510(k) are all premarket submissions for the approval of medical devices. "A 510(k) is a premarketing submission made to FDA to demonstrate that the device to be marketed is as safe and effective … [as] a legally marketed device that is not subject to premarket approval (PMA)." http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/default.htm. A PMA "is the most stringent type of device marketing application required by FDA. A PMA is an application submitted to FDA to request approval to market. Unlike premarket notification [*i.e.*, a 510(k)], PMA approval is to be based on a determination by FDA that the PMA contains sufficient valid scientific evidence that provides reasonable assurance that the device is safe and effective for its intended use or uses." http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/default.htm. An IDE is an investigation device exemptions, which is obtained to allow the use of a medical device in clinical studies. *See* http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/.

[5] Indeed, Plaintiffs' logic suggests that Ms. Kuehn's testimony should be excluded but Mr. Becze's should be admitted.

subordinate clauses such as, "in violation of the QSRs." *See, e.g.*, Exh. 1 to Briley Decl. at 12, 32. Ms. Kuehn does not identify her methodology or explain why it is reliable for evaluating compliance with the QSRs. She does not identify her methodology for determining whether documents are missing required information or are otherwise deficient. Ms. Kuehn "offers conclusions without explaining the reasoning or methodology by which [s]he reaches them, and indeed without any indication that [s]he applied the intellectual rigor the Supreme Court contemplated in *Kumho Tire*." *Donnelly v. Ford Motor Co.*, 80 F. Supp. 2d 45, 50 (E.D.N.Y. 1999). Where the proffered expert opinion is "connected to the existing data only by the *ipse dixit* of the expert," it is inadmissible. *See Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 157 (1999); *see also Grdinich v. Bradlees*, 187 F.R.D. 77, 82 (S.D.N.Y. 1999) ("Because 'knowledge connotes more than subjective belief or unsupported speculation,' there is no reliable foundation for [the] expert opinion.") (citing *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 590 (1993)).

Significantly, Plaintiffs retained another expert who is qualified to opine about ADI's regulatory compliance—Timothy A. Ulatowski. Mr. Ulatowski "was employed by the FDA from November 1974 until January 2011." Exh. 16 to Briley Decl. (Expert Report of Timothy A. Ulatowski, July 3, 2013 ("Ulatowski Report")), at 3. For most of that time—1980 to 2011—Mr. Ulatowski was employed in the Center for Devices and Radiological Health ("CDRH"), which oversees medical device manufacturers. *Id.* at 4-6. From 2003 to 2011, Mr. Ulatowski was the Director of the Office of Compliance, a division of CDRH, and was in charge of medical device manufacturing facility inspections. *Id.* at 6. Unlike Ms. Kuehn, Mr. Ulatowski would have had sufficient knowledge, education, experience and skill to render an opinion about a medical device manufacturing facility's compliance with the QSRs. However, Plaintiffs did not

ask Mr. Ulatowski to opine about ADI's regulatory compliance. *See* Exh. 17 to Briley Decl. (Deposition Transcript of Timothy A. Ulatowski, Aug. 15, 2013), at 121:11-125:11. Instead, they asked him to opine only about the 2009 Femtelle 510(k). *Id.*; *see also* Exh. 15 to Briley Decl. at 24. This circumstance can only mean that an experienced FDA compliance expert, such as Mr. Ulatowski (or Defendants' expert, Mr. Becze) would disagree with Ms. Kuehn's untutored and incompetent opinions.

CONCLUSION

For the foregoing reasons, Defendants respectfully request that the Court grant their motion *in limine* to exclude the report and testimony of Carrie M. Kuehn.

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